



Advancing Transfusion and
Cellular Therapies Worldwide

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Comments to Docket: Response

Docket 2004D-0198, *Guidance for Industry: Acceptable for Full-Length Donor History Questionnaire and Accompanying Materials for Use In Screening Human Donors of Blood and Blood Components; Draft Guidance.*

The AABB Donor History Task Force wishes to acknowledge and respond to those comments that were filed with regard to the accompanying materials published as appendices.

Several comments were received asking for clarification on whether facilities may alter the educational materials, the questionnaire, or the medication list. The User Brochure has been revised to provide more information and now has a section discussing DHQ Structure and Content and a separate section to address format issues. The Task Force recommends that the wording and the order of the documents should not be changed. A space at the end of the questionnaire, designated as additional questions, was created for use if a collection facility chooses to add "local questions." Blood centers are permitted to add local medication deferrals to the end of the Medication Deferral List. The Blood Donor Educational Materials are to be implemented in the wording presented in the draft guidance. The Task Force intended to permit the addition of identifying information such as blood center name and contact information. Note that the "formatting" of these documents may be determined locally; for instance, use of different fonts, single column vs. multiple columns, single page vs. multiple pages etc.

Appendix 7 – Blood Donor Educational Materials

One comment objected to the explicit definitions for vaginal sex, oral sex, and anal sex, stating that these definitions will not be appropriate at some locations such as high schools and churches. All materials were subjected to a rigorous evaluation, first by focus groups,

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including high school students and a church group, and then by Cognitive Interviews conducted by the National Center for Health Statistics, Centers for Disease Control and Prevention.

The focus group and NCHS cognitive interview participants identified the lack of a definition of “sexual contact” as a key deficiency in the donor screening process.

Both the focus groups and the NCHS interviewees repeatedly and overwhelmingly expressed the need to have a definition of sexual contact in the context of blood donation suitability. These observations are supported by a number of additional studies. Therefore, the task force has included specific definitions for sexual contact in the educational materials. Despite similar concerns, one large blood center has found that the donor groups have accepted explanation of the need for the explicit language, and blood drives have run without problem.

Appendix 1 – Full Length Donor History Questionnaire

Several comments suggested changes to various questions. **One comment suggested that questions 2 and 3 should be combined into one question.** One of the major Task Force goals is to simplify the wording and questions of the DHQ, using principles of survey design, to improve donor comprehension. Compound and multi-item questions were replaced by questions using the simplest wording possible with the intent of soliciting target information in the most direct way.

Another comment noted that Question 6 is not consistent with AABB Standards. Cognitive interviewing indicated that donors are able to remember certain time periods better than others. For example, donors can remember 48 hours quite well, but have more difficulty remembering 36 hours, so the question was changed to 48 hours. However, the *AABB Standards for Blood Banks and Transfusion Services* does state that the time period is 36 hours. If a donor answers “yes” to the 48-hour question, but the collection facility is able to establish that the time period was actually 36 hours, the donation could be used as the sole source of platelets., This information was added as a note in the flow chart.

One comment suggested that Questions 23, 24, and 39 should use the term “viral hepatitis.” One of the major goals of the Task Force is to simplify the wording of the questions, and use language that is understandable to the donor. Donors understand the term hepatitis, but may be confused by the term “viral hepatitis.” However, the Task Force agrees that the questions are intended to apply to viral hepatitis and has revised the donor eligibility statements and the flow charts to refer to viral hepatitis. Furthermore, the question asks about history of viral hepatitis without regard to the nature of the hepatitis. This is not a decision that can be determined by the facility medical director. In meetings with AABB, FDA has indicated that in order for a donor (who answers “yes” to this question) to donate, FDA would need to review the hepatitis history of the donor. Medical Directors are advised to contact the Blood and Plasma Branch of the FDA to discuss eligibility of donors with a ‘history of hepatitis’

One comment questioned why Canada was included in question 29, noting that asking about travel to Canada was important during the SARS outbreak. At the time the questionnaire was originally being developed, SARS was not a concern. At the present time, SARS is also not a concern. However, should it become necessary to inquire about travel to Canada, the Task Force will evaluate the appropriate method to obtain this information, and will advise questionnaire users of that information.

One comment questioned why “close contact” with hepatitis is not included in the questionnaire. The term “close contact” is vague and the Task Force elected to elicit the necessary information by asking more specific questions relating to “sexual contact” and “living with.” This specific wording is based on specific risks that have been identified as true risks by epidemiologic data, and was suggested by the CDC hepatitis experts working with the Task Force. These questions were well understood by the NCHS cognitive interview participants.

Appendix 3 - Glossary

One comment noted that “residing in” the same dwelling should be differentiated from “visiting” in the definition of lived with. This specific wording was suggested by the CDC hepatitis experts working with the Task Force. The Task Force believes that this distinction is clear and does not require a change in the glossary.

Appendix 2 – Donor History Questionnaire User Brochure

Two comments noted that completion of the entire questionnaire prior to determination of eligibility is unnecessary, and that donors should be permitted to defer at any time. The User Brochure states that donors should be instructed to complete all questions on the questionnaire. The Task Force anticipated that the questionnaire would be self-administered. In that case, the donor may not be able to determine whether they will be deferred until the questionnaire is reviewed with a donor historian, so they should be instructed to complete the entire questionnaire. However, the Task Force recognizes that there are situations in which the entire questionnaire may not be completed, and this is acceptable. For example, the donor may choose not to complete the entire questionnaire, or the blood center may choose to make an eligibility decision prior to completion of the entire questionnaire. The brochure stresses that “A knowledgeable historian shall be available to the prospective donor to answer any questions concerning eligibility or the donation process.” Should the donor discuss a question with the historian, prior to completing the questionnaire, the donor may elect not to complete the questionnaire, especially if he/she realizes that he/she is not eligible to donate. The Brochure also advises that, “The method of administration of the DHQ should be in accordance with the blood center’s SOP.” If the questionnaire is not self-administered, but is administered by a donor historian, then the local SOP may permit an eligibility decision to be made at any point during the interview and all questions may not be completed.

However, the Task Force wishes to point out that there might be an advantage to having the entire questionnaire completed. Some deferrals will be only temporary, but others are indefinite/permanent. Depending on the sequence of questions, a donor could be deferred temporarily, only to return at a later date and discover that he/she is permanently deferred due to the answer to another question that was not answered during the first visit

Appendix 4 - Flow Charts

Several comments question whether use of the flow charts should be a requirement.

The Task Force did not intend to require use of the flow charts that are included as part of the donor history questionnaire user brochure. The User Brochure was intended to provide instructions for how to use the materials. The flow charts were included as an example of how to expand on and investigate the response to the required capture question.

Each collection establishment is responsible for meeting donor eligibility criteria. While the Task Force encourages use of the flow charts, we anticipate that users will modify them to reflect local policies. Users may even wish to incorporate the flow charts into their SOPs. One commenter suggested the use of IF/THEN statements as a guide in conjunction with standard operating procedure. This would accomplish the same purpose as the flow chart, and the Task Force has no objection to that approach.

The Task Force has asked FDA to be more explicit that use of the flow charts is not required when it issues the final guidance.

One comment questioned the use of “defer donor” instead of “defer donor per SOP” as used in the flow charts for questions 7, 21, 23 and 24. The purpose of the statement “defer per SOP” is to identify situations in which the decision about permitting donation is known to be variable. Different facilities will make different decisions, depending on the institutional policy, and this policy should be spelled out in the SOP. The phrase “Defer Donor” was used when it was the Task Force’s understanding that FDA and/or AABB Standards require deferral. The Task Force recognizes that there may be special circumstances that the medical director will need to review, and the phrase “defer donor” is not intended to preclude such evaluation. However, when a particular requirement is delineated by the FDA, either in regulation or guidance, the Task Force believes that the decision to defer or accept is not routinely subject to medical director discretion. The Task Force modified the flow charts for questions 23 and 24 to read, “defer donor per SOP” as these questions do require further evaluation of the donor.

Question 9 – One comment requested that question 9 be deleted from the questionnaire stating that the flow chart runs the risk of being inaccurate and too confusing. The question is intended to be a broad capture question to indicate that additional information must be evaluated. The flow chart itself advises to determine the type of donation, the date of donation and consult SOP for eligibility. The Task Force revised the eligibility statement to clarify donor eligibility. The statement now reads, “A whole blood donor may donate no more frequently than every 8 weeks; plasma, platelets or leukapheresis donors may donate no more frequently than every 2 days.”

One comment suggested that if the answer to “Is the donor eligible?” is “no,” this should result in deferral of donors who are not eligible, and the instruction to defer per SOP should be changed to “defer donor.” The Task Force agrees that an ineligible donor would be deferred; however, the flow chart instructs the user to consult SOP for eligibility, and the Task Force wanted to emphasize that deferral policies should be defined in the SOP and deferral should be based on the SOP.

Question 18 – One comment suggested that the flow chart for question 18 should include a link referring to question 36 for questions involving male-to-male sex. The Task Force believes that while the subject matter of the two questions are related, it is not necessary to include a link because the questions address separate concerns.

Questions 47 and 48. One comment noted that there are tests other than antibody tests approved by the FDA to include a claim for detection of Group O viruses, such as Nucleic Acid Tests, and requested that the special note permitting deleting these questions be revised. The Task Force agrees, and has changed the note (indicated by ** beneath the flow chart) to read, “Blood collection agencies using an HIV test that has been approved by the FDA for donor screening to include a claim for detection of Group O viruses may eliminate this question during screening.”

Appendix 4 - Flow Charts/Donor Eligibility Statements

The donor eligibility statements were intended to provide a reference explaining the basic reason for the particular requirement. The Task Force has revised a number of the statements, based on the comments received.

Question 1 – One comment suggested that a donor with a cold may donate and requested that the statement delete the reference to colds. During discussion of the CFR requirement to screen for acute respiratory illness, the FDA requested that donors be asked about respiratory symptoms and recent colds. Rather than add a specific question, the Task Force elected to capture this information by asking “Are you feeling healthy and well today?” The discussion is also reflected by the inclusion of colds in the donor eligibility statement.

Question 2 – One comment suggested that the statement includes donors taking all types of antibiotics and would unnecessarily defer donors that are using a topical antibiotic or have fungal infections such as Athlete’s Foot. The second part of the eligibility statement explains that the reasons for antibiotic use must be evaluated to determine if the donor has a bacterial infection that could be transmissible by blood and leaves specific deferral criteria up to local control.

Question 8 – One comment noted that there is no medical reason to defer donors who have had a miscarriage or abortion in the first and second trimester. The Task Force originally considered deletion of this question, but consulted with the American College of Obstetrics and Gynecology (ACOG) for advice. ACOG was unable to clearly agree that the question could be deleted so the Task Force retained the question. Note that the flowchart advises to “defer donor per SOP,” so flexibility in local policy for deferral for miscarriage or abortion is anticipated.

Question 9 – One comment found the statement confusing. The Task Force agrees and has changed the statement to read, “A whole blood donor may donate no more frequently than every 8 weeks. Plasma, platelets, and leukapheresis donors may donate no more frequently than every 2 days.”

Question 10 – One comment asked whether the original statement implied that the person could never donate again. The Task Force did not intend to imply that and has changed the statement to read, “Certain vaccinations may contain live infectious agents. A donor who has been exposed to live infectious agents may not be eligible to serve as a donor for a specified period of time.”

Question 21 – One comment suggested rewording the statement to read, “any person with hemophilia or related clotting disorders who has been treated with factor concentrates.” The Task Force disagrees. Note that question 21 contains two separate conditions. The donor eligibility statement is intended to denote two separate categories, hemophiliacs or persons with related clotting disorders as well as any person who has received clotting factor concentrates. A donor meeting either criterion would be deferred; that is, sexual contact with a hemophiliac who has not received clotting factors would still be deferred.

Question 25 – One comment noted that the donor eligibility statement as written conflicts with criteria in AABB Standards. The Task Force agrees and has revised the eligibility statement to read, “Persons who have had a tattoo in the previous 12 months are deferred for 12 months from the date of the tattoo application, unless tattoos have been applied using sterile techniques at a facility licensed by the state.”

Question 32 and 33 – One comment noted that the risk of developing vCJD through blood transfusion is no longer theoretical. The Task Force agrees and has changed the eligibility statement to delete the word “theoretical;” i.e., “There may be a risk of developing vCJD through blood transfusion.”

Question 39 – One comment suggested that donors with a history of CMV or EBV (mononucleosis) hepatitis are eligible to donate. The question asks about history of viral hepatitis without regard to the nature of the hepatitis. This is not a decision that can be determined by the facility medical director. Medical Directors are advised to contact the Blood and Plasma Branch of FDA to discuss eligibility of donors with a “history of hepatitis.”

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